II

119TH CONGRESS
2D SESSION

S. 4066

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug mifepristone for the purpose of the termination of intrauterine pregnancy is deemed to have been withdrawn, to establish a Federal tort for harm to women caused by chemical abortion drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

MARCH 11, 2026

Mr. HAWLEY introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To provide that the approved application under the Federal Food, Drug, and Cosmetic Act for the drug mifepristone for the purpose of the termination of intrauterine pregnancy is deemed to have been withdrawn, to establish a Federal tort for harm to women caused by chemical abortion drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Safeguarding Women from Chemical Abortion Act''.

SEC. 2. WITHDRAWAL OF APPROVAL OF THE DRUG MIFEPRISTONE FOR TERMINATION OF PREGNANCY.

Effective upon the expiration of 14 days after the date of the enactment of this Act:

(1) Approval of an application submitted under subsection (b) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for the drug mifepristone (marketed as Mifeprex, and also known as RU–486) with an indication for the termination of intrauterine pregnancy, and of any application submitted under subsection (j) of such section for a drug with the same indication and for which mifepristone is the reference drug, is deemed to have been withdrawn under subsection (e) of such section.

(2) For purposes of sections 301(d) and 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(d); 334), the introduction or delivery for introduction of a drug, the approval of which has been withdrawn as described in paragraph (1), into interstate commerce shall be considered a violation of section 505 of such Act (21 U.S.C. 355).

(3) The drug mifepristone shall be considered misbranded for purposes of sections 301 and 304 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331; 334) if the drug bears labeling pro-

viding that the drug may be used for the termination of intrauterine pregnancy or that the drug may be used in conjunction with another drug for the termination of intrauterine pregnancy.

SEC. 3. FEDERAL TORT FOR HARM TO WOMEN CAUSED BY CHEMICAL ABORTION DRUGS.

(a) DEFINITIONS.—In this section:

(1) COVERED ENTITY.—The term ''covered entity'' means a person that manufactures a covered medication for introduction into interstate commerce.

(2) COVERED MEDICATION.—The term ''covered medication'' means the drug mifepristone (marketed as Mifeprex, and also known as RU–486), with an indication for the termination of intrauterine pregnancy, approved pursuant to an application submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

(b) LIABILITY.—A covered entity shall be liable in accordance with this section to any individual who suffers bodily injury or harm to mental health (including any physical, psychological, emotional, or physiological harm) that is attributable, in whole or in part, to the individual's

use of a covered medication manufactured by a covered entity.

(c) PRIVATE RIGHT OF ACTION.—An individual who suffers bodily injury or harm to mental health that is attributable, in whole or in part, to the individual's use of a covered medication as described in subsection (b) may bring a civil action against the covered entity in an appropriate district court of the United States or a State court of competent jurisdiction for—

(1) compensatory damages;

(2) punitive damages; and

(3) attorney's fees and costs.

(d) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to preempt any State law that makes available any other remedy to an individual described in subsection (b).

(e) EFFECTIVE DATE.—This section shall take effect on the date that is 90 days after the date of enactment of this Act.

SEC. 4. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to affect any provision of section 1461 of title 18, United States Code.

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